

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-066/S010

CHEMISTRY REVIEW(S)

File 20-066

557.1

JUN 6 2000

CHEMIST REVIEW
OF SUPPLEMENT

1. ORGANIZATION HFD-560
2. NDA NUMBER: 20-066
3. SUPPLEMENT NUMBERS/DATES: SCF-010

Letter date: 2/21/2000

Stamp date: 2/22/2000

Due date: 6/22/2000

4. AMENDMENTS/REPORTS/DATES: BC

Letter date: 3/15/, 4/28, 5/1/2000

Stamp date: 3/16/, 5/1, 5/2/2000

5. RECEIVED BY CHEMIST: 3/2/2000

6. APPLICANT NAME AND ADDRESS: SmithKline Beecham Consumer Healthcare
1500 Littleton Road
Parsippany, NJ 07054-3884

7. NAME OF DRUG: Nicorette® 4 mg Gum
8. NONPROPRIETARY NAME: nicotine polacrilex
9. CHEMICAL NAME/STRUCTURE: see USP
10. DOSAGE FORM(S): chewing gum
11. POTENCY: 4 mg/piece
12. PHARMACOLOGICAL CATEGORY: Stop smoking aid
13. HOW DISPENSED: OTC
14. RECORDS & REPORTS CURRENT: yes
15. RELATED IND/NDA/DMF: NDA 18-612/S-028 and attached list of DMFs.
16. SUPPLEMENT PROVIDES FOR: the addition of an orange flavored gum.
17. COMMENTS:

This supplement provides for the addition of orange flavored gum to the Nicorette® line. This review covers the small amount of information provided by _____ (the manufacturer) to the NDA holder, SKB. The majority of the information is in _____ DMFs (see next page).

18. CONCLUSIONS AND RECOMMENDATIONS:

APPROVE contingent on acceptable review by the other disciplines.

19. REVIEWER NAME

Charlotte Yaciw

SIGNATURE

/S/

DATE COMPLETED

6/5/2000

6/6/00

Concurrence: Mona Zarifa

cc: Original: NDA 20-066

HFD-560/Division File

HFD-560/PM/DKeravich

HFD-550/Chem/CYaciw

HFD-830/Dir/CWChen

/S/

HFD-560/DepDir/LKatz

HFD-550/ChemTL/MZarifa

AUG 18 2000

**CHEMIST REVIEW #2
OF SUPPLEMENT**

- 1. ORGANIZATION** HFD-560
- 2. NDA NUMBER:** 20-066
- 3. SUPPLEMENT NUMBERS/DATES:** SCF-010
Letter date: 2/21/2000
Stamp date: 2/22/2000
Due date: 11/12/2000 (for AZ)
- 4. AMENDMENTS/REPORTS/DATES:** AZ (*et al.*)
Letter date: 7/10/2000
Stamp date: 7/12/2000
- 5. RECEIVED BY CHEMIST:** 7/19/2000

6. APPLICANT NAME AND ADDRESS: SmithKline Beecham Consumer Healthcare
1500 Littleton Road
Parsippany, NJ 07054-3884

- 7. NAME OF DRUG:** Nicorette® 4 mg Gum
- 8. NONPROPRIETARY NAME:** nicotine polacrilex
- 9. CHEMICAL NAME/STRUCTURE:** see USP
- 10. DOSAGE FORM(S):** chewing gum
- 11. POTENCY:** 4 mg/piece
- 12. PHARMACOLOGICAL CATEGORY:** Stop smoking aid
- 13. HOW DISPENSED:** OTC
- 14. RECORDS & REPORTS CURRENT:** yes
- 15. RELATED IND/NDA/DMF:** NDA 18-612/S-028
- 16. SUPPLEMENT PROVIDES FOR:** the addition of an orange flavored gum.
- 17. COMMENTS:**

This supplement provides for the addition of orange flavored gum to the Nicorette® line. This amendment was submitted in response to the Approvable Letter dated 2/21/2000 and contains an addendum to the stability report. The corrections pertain to the description of the foil lidding used in the blister packs. No data were affected. The corrections do not change the initial assessment of the supplement.

18. CONCLUSIONS AND RECOMMENDATIONS:

APPROVE contingent on acceptable review by the labeling staff.

19. REVIEWER NAME
Charlotte Yaciw

SIGNATURE

DATE COMPLETED

/S/

8/8/2000

/S/

8/8/00

Concurrence: Mona Zarifa
cc: Original: NDA 20-066
HFD-560/Division File
HFD-560/PM/DKeravich
HFD-550/Chem/CYaciw
HFD-830/Dir/CWChen

HFD-560/DepDir/LKatz
HFD-550/ChemTL/MZarifa
